COVINGTON & BURLING

CONFIDENTIAL

March 15, 1982

To: Messrs. Greer
Henson
Holtzman
Pepples
Stevens
Witt

Re: Meeting with HHS Assistant Secretary Brandt on March 10

At 2 p.m. on Wednesday, March 10, 1982, Horace Kornegay and I met with Assistant Secretary for Health Edward N. Brandt, Jr., Joanne Luoto, M.D., Acting Director of the Clearinghouse on Smoking and Health, and Richard Riseberg, an HHS attorney. The meeting, which was to discuss our proposal of November 9, 1981 and HHS's comments on the proposal contained in Secretary Brandt's letter of January 8, 1982, lasted about one and a quarter hours.

Secretary Brandt opened the meeting by stating that there had been a good deal of press interest in additives in the past few weeks; and that he had taken the position with the press that the industry was concerned about the trade secret problem and that HHS and the industry were currently engaged in discussions of the matter. After Horace's reference to the statement to this effect at the HHS press conference on the Surgeon General's report, Brandt stated that there had been more press inquiries and implied that one or more additional articles might appear. The Secretary added that he had no intention of trying to use the press to resolve this question; he said that he had lost every time he had used the press.

Brandt then suggested that we go through the points which had been raised in his January 8, 1982 letter.

1. With respect to points 1 and 2 of our November 9 letter, Brandt said that their biggest concern was with what we would include in "commonly added." Dr. Luoto stated that they are basically interested in the measure of public exposure to any particular additive. She said an additive could be in dozens of brands and not be significant in the total; conversely, an ingredient could be in only one brand of one company and still be a main constituent.

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Secretary Brandt and Dr. Luoto suggested that perhaps the matter could be approached by looking at individual companies and the additives submitted for the brands that accounted for some percentage, such as 60 percent, of the company's sales. Our response was that we certainly had to stay away from ingredients in particular brands since this was information that was the most sensitive and most closely guarded in each company. We suggested that any attempt to approach the matter by particular brands or companies would not work because the companies would find this approach flatly unacceptable.

After stating that I had discussed the matter in general terms with some knowledgeable people in the industry, I said that HHS was probably constructing a problem where one really did not exist. In elaboration, I said that it was my feeling -- based on these preliminary conversations -- that probably about a dozen ingredients were all that were "commonly used" and that these ingredients probably accounted for 90 percent or more of the total amount of ingredients added to cigarettes. We said that these ingredients were really all that came within the purview of the term "commonly used," but that we were not insisting on this limitation. We added that we thought we could prevail upon the cigarette manufacturers to agree to submit the name of any ingredient that was used by three or more of the six companies.

Secretary Brandt indicated that he thought that this would be a satisfactory approach but that the problem remained as to how they could learn of some "uncommon item" that still appears in large quantity or, as he also phrased it, an "uncommon item that is commonly used." Our response was that we did not believe that this would actually present a problem if we could secure approval to submit to HHS a list of the "commonly used" ingredients, plus other ingredients that were used by three or more companies. It was left, however, that we would explore with the companies some way to assure HHS that this type of list would not omit an ingredient that, even though not used by three or more companies, was used to an important extent by even one company.

2. Brandt then skipped to the point contained in the last paragraph on page 1 of his January 8 letter, stating that it would be very helpful if the companies provided HHS with toxicity data on the items listed. Horace stated that it would be better to have HHS come back to us with a request for toxicity data if they had questions about a particular item or items on the list. We pointed out that we were confident that most items on the list would raise no question, and that it made no sense to have to assemble material that HHS really did not need. Secretary Brandt expressed agreement with the Kornegay suggestion.

3. Secretary Brandt then turned to point 4 of our proposal, which limited access to the list to representatives and officials of the department, not exceeding four in number. He had a real problem with this since he believed he would have to consult with experts outside the Department for toxicity or other scientific review. He added that they have good toxicity capabilities within the Department (e.g., at NIH) but that he was not sure he wanted to use HHS scientists in this project. His stated reason was that, if he were to use HHS scientists, he would run into an issue of scientific freedom and he would have difficulty in having them understand the confidentiality requirements. If he used a qualified outside academic expert, he could get the expert to agree by contract to the confidentiality requirements.

Secretary Brandt and Riseberg confirmed that any such outside consultant would be classified as a "special government employee" and would be subject to the same Governmental legal restrictions on violating confidentiality as any full-time Government official or employee.

Secretary Brandt elaborated at this point on his views as to how he would like to proceed. He indicated that if there was something unusual or questionable on the list he would need expert outside advice. As an example, he mentioned paraquat (the substance which has been sprayed on marijuana to make it unusable for smoking) and said that you can drink paraquat without much harm, but that if you burn and inhale it, it becomes a severe toxin. He said review of the additives list would require the availability of expert advice. Secretary Brandt said his goal was to have probably only one person with access to the entire list at the C&B offices and that any single item on that list could be shared with not more than three other persons. None of these other persons would know or be advised as to the source of the material. He appeared later to back away from the position that only one person would have access to the C&B list, stating that he felt he could live with a maximum of eight people having access to any material on the list, with not more than four seeing any one item. Secretary Brandt also stated that one HHS employee would have responsibility for seeing that any materials would be maintained in one place with complete security.

There was some further discussion in which we tried to reduce the number of people with access, but we did not press the point vigorously.

The HHS group also raised the question of how they were expected to operate if they were prohibited from copying the list, particularly in view of the restrictions on taking notes. We said that we clearly did not want any copies of the

list made, but that we recognized that some procedure would be needed and that we did not expect the HHS person with access to be required to memorize the list.

4. With respect to point 6, Riseberg, the HHS lawyer, took over and said that it was not in HHS's powers to agree that its denial of an FOI request would be defended in court, because the Department of Justice, and not HHS, would decide how far the Government would go in defending the matter in court. He said that HHS could agree to classify all the materials as coming within Exemption 4 of the FOIA (the confidential information section), to deny any request for disclosure under the FOIA, to notify the industry of any such request, and to do what it could to resist access to the materials. It was left that Riseberg would check with Justice to see what kind of assurances, if any, he could obtain from Justice that it would defend in court HHS denials of access.

5. Secretary Brandt said that point 7, and the related points 8 and 9, raised a "really significant problem" for HHS. He said that suppose HHS found a deadly toxin on the list; under point 7 it was clear that HHS could not say anything. He said HHS was willing to agree that it would not say anything publicly without prior discussion with the industry, but that he could not agree to something which would prevent HHS from dealing with any matter that it viewed as a serious public health problem. He returned to his example of paraquat, observing that this was a known toxin to man and that if there were something like this on the list, HHS would have to be free to take some action if it had what it considered good evidence that the item was harmful.

Our rejoinder was that this problem is more theoretical than real. Horace said that he believed firmly that there would be nothing like paraquat on the list and that we thought the procedures outlined in points 7, 8 and 9 of our letter would work well in practice. It was our expectation that most items on the list would raise no concerns, and if any item or items really raised legitimate questions in their minds, they would be discussed with the industry pursuant to points 8 and 9. It would be our hope that these discussions would satisfy HHS that the items presented no problem and, if after such discussions, HHS persisted in the view that there was a serious problem with an ingredient, we would expect the industry to stop using it. Horace mentioned that one reason for our proposing the procedure set forth in points 7-9 was that we had been unfairly hit in the past by leaks and non-scientific disclosures, and that it was necessary to avoid any repetition of this.

Secretary Brandt said that he had no intention of using "scare tactics" but that they were still concerned with this problem of having the Government's hands tied, and that they would come back to us with some alternative suggestions.

6. At the conclusion of the meeting, the Secretary said that in his appearance scheduled for the following morning (March 11) before the Waxman subcommittee, he planned to respond to any questions on additives by stating that he was participating in ongoing discussions with the industry and he thought that they were progressing in good faith.

7. There was no discussion of when we would again be in contact. The general impression was that we would discuss with the companies the points raised during the meeting, that we would hear from HHS on Riseberg's contact with Justice, possibly on any ideas he had about the provisions dealing with access to the list, and that we would also receive some suggestions on the question of HHS's being completely prohibited from going public on any item.

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